K041639

SEP - 2 2004

Envisioneering

Section 2

510(k) Summary

1. **Applicant:** Envisioneering, LLC
1982 Innerbelt Business Center Drive
St. Louis, MO 63114

Contact Person: Tom Kappel
Telephone: 314-429-7367
FAX: 314-429-7701

2. **Date Prepared:** March 22, 2004

3. **Trade Name:** TargetScan™ Transrectal Ultrasound System

4. **Common Name:** Diagnostic Ultrasound System with Accessories

5. **Establishment Registration Number:** pending

6. **Establishment Address:** Envisioneering, LLC
1982 Innerbelt Business Center Drive
St. Louis, MO 63114

7. **Classification Names:** This system is a Class II device.

Ultrasound Pulsed Echo Imaging System, (21 CFR 892.1560; Procode: IYO)

8. **Identification of Predicate Device(s):**
The predicate device for the ultrasound probe and system is:
   - Carolina Medical Proscan® and Proscan® Plus Urological Ultrasound Imaging systems (Teknar K864807)

9. **Device Description:**
The TargetScan™ Transrectal Ultrasound system is intended for diagnostic prostate applications. The TargetScan™ Transrectal Ultrasound system allows the probe to remain stationary inside the patient while the user controls the position of the scan planes that are displayed on the monitor. The probe design allows the capture of transverse and longitudinal scan planes. The system is PC based allowing comprehensive imaging, planning, targeting and data storage/ retrieval.

1982 Innerbelt Business Center Drive, St Louis, MO 63114 Ph: 314.429.7367 Fax: 314.429.7701

10. Intended Use

Purpose and Function of the Device
This Ultrasound imaging system is intended for transrectal diagnostic imaging of the prostate gland. This imaging can be used to guide other procedures such as biopsy of the prostate.

Intended Patient Population
This system is intended to be used with adult patients.

Intended Environment of Use
This system is intended for use by medical professionals in a physician office or hospital environment.

11. Technological Characteristics compared to those of the Predicate Device

Both the subject and predicate devices:

- are intended for transrectal diagnostic imaging of the prostate gland.
- are similar in external design
- can image the prostate in the longitudinal and transverse plane and can display both views simultaneously on the display.
- allow biopsy targeting by indicating the needle path on the displayed image

The subject device allows the scanning of the whole prostate without moving the probe in the patient, as the transducer itself moves inside the probe.

12. Testing

This device will be tested against and will comply with the following standards.

- IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- EN60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
- UL2601-1, Standard for Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-2-37 – Medical Electrical Equipment – Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- IEC 60601-1-2 – Medical Electrical Equipment – Part 1: General Requirements for Safety, 2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

Envisioneering, LLC
% Ms. Chantel Carson
Section Manager
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
NORTHBROOK IL 60062, USA

Re: K041639
Trade Name: TargetScan Transrectal Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: August 19, 2004
Received: August 23, 2004

Dear Ms. Carson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the TargetScan Transrectal Ultrasound System, as described in your premarket notification:

Transducer Model Number

TS-360-P

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21

CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K041639

Diagnostic Ultrasound Indications for Use Form
TargetScan Ultrasound System – Model TS-360aSYS

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode** of Operation						
(Track I Only)	(Tracks I and III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative							
	Neurological							
	Pediatric							
	Small Organ (prostate)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Transesophageal							
	Transrectal	N						
	Transvaginal							
	Transurethral							
	Intravascular							
	Laparoscopic							
	Musculo-skeletal							
	Musculo-skeletal Superficial							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (specify)							
Peripheral Vessel	Peripheral Vascular							
	Other (specify)							

* examples may include: A-mode, amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue motion Doppler, color velocity imaging

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments: ___

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041639

Diagnostic Ultrasound Indications for Use Form

TargetScan rectal probe – Model TS-360-P 510(k) Number: K041639

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
(Track I Only)	(Tracks I and III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative							
	Neurological							
	Pediatric							
	Small Organ (prostate)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Transesophageal							
	Transrectal	N						
	Transvaginal							
	Transurethral							
	Intravascular							
	Laparoscopic							
	Musculo-skeletal							
	Musculo-skeletal Superficial							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (specify)							
Peripheral Vessel	Peripheral Vascular							
	Other (specify)							

* examples may include: A-mode, amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue motion Doppler, color velocity imaging

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: ___

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

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